

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ANITA HOCHENDONER; EARL
HOCHENDONER; ANITA BOVA;
JOSEPH M. CARIK; BARBARA J.
CARIK; AMBER BRITTON; SHAWN
BRITTON; CHERYL BRITTON;
THOMAS OLSZEWSKI; DARLENE
COOKINGHAM; and DAVID ROBERTS,)

Individually and on behalf of all others
similarly situated,

Plaintiffs,

v.

GENZYME CORPORATION; and
MOUNT SINAI SCHOOL OF
MEDICINE OF THE CITY UNIVERSITY
OF NEW YORK,

Defendants.

Civil Action No. 2:11-CV-00313-CB

**BRIEF IN SUPPORT OF DEFENDANTS' MOTION (A) TO DISMISS AS TO
DEFENDANT MOUNT SINAI SCHOOL OF MEDICINE FOR LACK OF PERSONAL
JURISDICTION, (B) TO DISMISS FOR FAILURE TO STATE A CLAIM UPON
WHICH RELIEF CAN BE GRANTED, AND (C) TO TRANSFER ANY SURVIVING
CLAIMS TO MASSACHUSETTS**

Table of Contents

	Page
I. MT. SINAI MUST BE DISMISSED FOR LACK OF PERSONAL JURISDICTION	3
A. Pennsylvania Lacks General Jurisdiction	4
B. Pennsylvania Lacks Specific Jurisdiction	4
II. AS A MATTER OF LAW, AND UNDER RELEVANT PLEADING STANDARDS, PLAINTIFFS' CLAIMS AGAINST GENZYME MUST BE DISMISSED	6
A. Plaintiffs' Negligence <i>Per Se</i> Count Fails As A Matter of Law	6
B. The Causes Of Action For Strict Liability Must Be Dismissed	7
C. Plaintiffs' Causes Of Action For Breach Of Express And Implied Warranties Fail As A Matter Of Law.	8
1. Plaintiffs Fail To Allege The Existence Of Any Express Warranty	8
2. Plaintiffs' Implied Warranty Claims Fail As A Matter Of Law..	9
D. The Bayh-Dole Act Does Not Establish An Implied Right of Action	10
E. Counts Alleging Statutory Violations Of State Consumer Protection Statutes Fail As A Matter Of Law.	11
1. Count VI Fails To State A Claim Under Pennsylvania Law	11
2. Counts VII And VIII Fail Under Nevada And Michigan Law, Respectively	11
3. Count IX Fails Under North Carolina Law	12
F. Plaintiffs' Claims Are Vague And Insufficiently Pled.	13
III. ANY REMAINING CLAIMS SHOULD BE TRANSFERRED TO THE DISTRICT OF MASSACHUSETTS.	15
A. This Action Could Have Been Brought In Massachusetts	17
B. The Private Interest Factors Weigh In Favor Of Transfer	17
1. The Balance Of The Parties' Preferences Favors Transfer	17
2. Plaintiffs' Claims Arose In Massachusetts	17
3. Massachusetts Is The More Convenient Forum For The Parties and Witnesses	18
4. Books, Records, And Key Sources Of Proof Are In Massachusetts	19
C. The Public Interest Factors Weigh In Favor Of Transfer	20

Table of Contents (cont'd)

	Page
1. Litigation In Massachusetts Involving The Same Facts Is A Practical Consideration Supporting Transfer.....	20
2. Massachusetts' Particularized Interests In A Local Controversy Favor Transfer.....	23
3. Massachusetts' Public Policy Interests Favor Transfer	23
4. Familiarity With Pennsylvania Law Would Not Provide A Significant Benefit.	24
CONCLUSION.....	25

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Alex Brown Sons v. Marine Midland Bank, Inc.</i> 96 Civ. 2549 (RWS), 1997 WL 97837 (S.D.N.Y. Mar. 4, 1997)	1
<i>Allison v. Merck and Co., Inc.</i> , 878 P.2d 948 (Nev. 1994)	7
<i>Ashcroft v. Iqbal</i> , 556 U.S. ___, 129 S. Ct. 1937 (2009)	13
<i>B.R. Tank, LLC v. Holcim (US), Inc.</i> , No. A-09-CA-640, 2009 WL 3831379 (S.D. Tex. Nov. 12, 2009)	23
<i>Baraukas v. Danek Med., Inc.</i> , No. 97-CV-00613, 2000 WL 223508 (M.D.N.C. Jan. 13, 2000)	6
<i>Bearden v. Wyeth</i> , 482 F. Supp. 2d 614 (E.D. Pa. 2006)	6
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007)	13, 14
<i>Billings v. GFTM, LLC</i> , 867 N.E.2d 714 (Mass. 2007)	21
<i>Brown v. Kia Motors Corp.</i> , No. 2:06-cv-804, 2007 WL 539652 (W.D. Pa. Feb. 15, 2007)	17
<i>Burkert v. Petrol Plus of Naugatuck</i> , 579 A.2d 26 (Conn. 1990)	5
<i>Candelaria v. B.C. Gen. Contractors, Inc.</i> , 600 N.W. 2d 348 (Mich. Ct. App. 1999)	6
<i>Ciba-Geigy Corp. v. Alza Corp.</i> , 804 F. Supp. 614 (D.N.J. 1992)	10
<i>CIBC World Mkts., Inc. v. Deutsche Bank Sec., Inc., et al.</i> , 309 F. Supp. 2d 637 (D.N.J. 2004)	22
<i>Circuit City Stores, Inc. v. Citgo Petroleum Corp.</i> , 1994 WL 483463 (E.D. PA)	1

Table of Authorities (cont'd)

	Page(s)
<i>Conradt v. Four Star Promotions Inc.</i> , 728 P.2d 617 (Wash. App. Div. 1986).....	15
<i>Cooney v. Rossiter</i> , 583 F.3d 967 (7th Cir. 2009)	14
<i>Coppola v. Ferrellgas, Inc.</i> , 250 F.R.D. 195 (E.D. Pa. 2008).....	23, 24
<i>Corrales Martin v. Clemson Univ.</i> , No. 07-CV-536, 2007 WL 4531028 (E.D. Pa. Dec. 20, 2007).....	4
<i>Creazzo v. Medtronic, Inc.</i> , 903 A.2d 24 (Pa. Super. Ct. 2006).....	11
<i>Dalton v. Camp</i> , 548 S.E.2d 704 (N.C. 2001).....	12
<i>Decker v. Marriott Hotel Servs.</i> , No. 06-3191, 2007 WL 1630097 (E.D. Pa. June 4, 2007).....	20
<i>Driggers v. Sofamor, S.N.C.</i> , 44 F. Supp. 2d 760 (M.D.N.C. 1999)	8
<i>Driscoll v. Matt Blatt Auto Sales</i> , No. 95-CV-5314, 1996 WL 156366 (E.D. Pa. Apr. 3, 1996).....	5
<i>Duronio v. Merck & Co.</i> , No. 267003, 2006 WL 1628516 (Mich. Ct. App. June 13, 2006)	12
<i>Duvall v. Avco Corp.</i> , No. 4:CV05-1786, 2006 WL 723484 (M.D. Pa. Jan. 30, 2006).....	18
<i>Fenner Inv., Ltd. v. Hewlett-Packard Co.</i> , No. 08-CV-273, 2010 WL 3275758 (E.D. Tex Apr. 15, 2010).....	10
<i>Francom v. Costco Wholesale Corp.</i> , 991 P.2d 1182 (Wash. App. Div. 2000).....	15
<i>Fujitsu Ltd. v. Tellabs, Inc.</i> , 639 F. Supp. 2d 761 (E.D. Tex. 2009).....	23, 24
<i>Gehling v. St. George's Sch. of Med., Ltd.</i> , 773 F.2d. 539 (3d Cir. 1985).....	4
<i>Gen. Elec. Co. v. Deutz AG</i> , 270 F.3d 144 (3d Cir. 2001).....	4

Table of Authorities (cont'd)

	Page(s)
<i>Greenberg v. Miami Children's Hosp. Research Inst., Inc.</i> , 208 F. Supp. 2d 918 (N.D. Ill. 2002)	4, 5
<i>Gregory v. Dillard's Inc.</i> , 565 F. 3d 464 (8th Cir. 2009) (en banc)	14
<i>Harbour Point Homeowners Assoc., Inc. v. DJF Enters., Inc.</i> , 697 S.E.2d 439 (N.C. Ct. App. 2010)	8
<i>Harrah v. J.C. Bradford & Co.</i> , 1994 WL 543528 (4th Cir. 1994)	13
<i>Heindel v. Pfizer, Inc.</i> , 381 F. Supp. 2d 364 (D.N.J.2004)	11
<i>Helicopteros Nacionales de Colombia, S.A. v. Hall</i> , 466 U.S. 408 (1984)	4
<i>Heritage Resources, Inc. v. Caterpillar Fin. Servs. Corp.</i> , 774 N.W.2d 332 (Mich. Ct. App. 2009)	8
<i>Hill v. Danek Med., Inc.</i> , No. 96-CV-177, 1998 WL 1048182 (E.D.N.C. Sept. 10, 1998)	6
<i>In re Aredia and Zometa Prod. Liab. Litig.</i> , No. 3-06-MD-1760, 2010 WL 5072022 (M.D. Tenn. Dec. 7, 2010)	6
<i>In re Diet Drugs Litig.</i> , No. 98-CV-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999)	6
<i>In re FEMA Trailer Formaldehyde Prods. Liab. Litig.</i> , 570 F. Supp. 2d 851 (E.D. La. 2008)	14
<i>In re Genentech, Inc.</i> , 566 F.3d 1338 (Fed. Cir. 2009)	16
<i>In re Orthopedic Bone Screw Prod. Liab. Litig.</i> , 193 F.3d 781 (3d Cir. 1999)	7
<i>In re Prempro Prods. Liab. Litig.</i> , 4:03-CV-1507-WRW, 4:04-CV-01202, 2008 WL 1699211 (E.D. Ark. Apr. 9, 2008)	9
<i>In re Wellbutrin XL Antitrust Litig.</i> , 260 F.R.D. 143 (E.D. Pa. 2009)	6
<i>Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee</i> , 456 U.S. 694 (1982)	3

Table of Authorities (cont'd)

	Page(s)
<i>Int'l Shoe, Co., v. Washington</i> , 326 U.S. 310 (1945).....	4
<i>Jim Walter Corp. v. Cont'l Cas. Co.</i> , No. 91-3583, 1992 WL 162851 (D.N.J. June 1, 1992).....	22
<i>Johnson v. Chrysler Corp.</i> , 254 N.W. 2d 569 (Mich. Ct. App. 1977)	8
<i>Jumara v. State Farm Ins. Co.</i> , 55 F.3d 873 (3d Cir. 1995).....	16, 17
<i>Kelley v. Jacobs</i> , No. 21953-1-II, 1999 WL 305232 (Wash. Ct. App. May 14, 1999)	8
<i>Kemp v. Pfizer, Inc.</i> , 835 F. Supp. 1015 (E.D. Mich. 1993).....	12
<i>Kester v. Zimmer Holdings, Inc.</i> , No. 2:10-CV-00523, 2010 WL 2696467 (W.D. Pa. June 16, 2010)	8, 9, 11
<i>Kettavong v. Gasbarre Prods., Inc.</i> , No. 07-00810, 2007 WL 2728413 (W.D. Pa. Sept. 17, 2007).....	18
<i>Klingensmith v. Paradise Shops, Inc.</i> , No. 07-322, 2007 WL 2071677 (W.D. Pa. July 17, 2007)	17, 18, 19
<i>Knipe v. SmithKline Beecham</i> , 583 F. Supp. 2d 602 (E.D. Pa. 2008)	6
<i>Laisure-Radke et al., v. Par Pharm., Inc.</i> , 426 F. Supp. 2d 1163 (W.D. Wash. 2006).....	8
<i>Lewis v. Casey</i> , 518 U.S. 343 (1996).....	14
<i>Long v. Chelsea Cmty. Hosp.</i> , 557 N.W.2d 157 (Mich. Ct. App. 1996)	15
<i>Ltd. Serv. Corp. v. M/V APL Peru</i> , No. 2:09-cv-1025, 2010 WL 2105362 (S.D. Ohio May 25, 2010).....	22
<i>Madey v. Duke Univ.</i> , 413 F. Supp 2d. 601 (M.D.N.C. 2006)	10
<i>Makripodis v. Merrell-Dow Pharm., Inc.</i> , 523 A.2d. 374 (Pa. Super. Ct. 1987).....	9

Table of Authorities (cont'd)

	Page(s)
<i>McLaurin v. East Jordan Iron Works, Inc.</i> , 666 F. Supp. 2d 590 (E.D.N.C. 2009).....	15
<i>McLichey v. Bristol West Ins. Co.</i> , 408 F. Supp. 2d 516 (W.D. Mich. 2006)	12
<i>Med. Corp. v. McGonigle</i> , 955 F. Supp. 374 (E.D. Pa. 1997)	5
<i>Middlesex Cnty. Sewage Auth. v. Nat'l Sea Clammers Assoc.</i> , 453 U.S. 1 (1981).....	10, 11
<i>Miller v. DePuy Spine, Inc.</i> 638 F. Supp. 2d 1226 (D. Nev. 2009).....	7, 8
<i>Mosteller v. Duke Energy Corp.</i> , 698 S.E. 2d 424 (N.C. Ct. App. 2010)	6
<i>Mylan, Inc. v. Boehringer Ingelheim Int'l</i> , No. 09-990, 2010 WL 1142040 (W.D. Pa. Mar. 24, 2010)	20, 22
<i>National Asset Mgmt. v. Coleman</i> , No. 10-16, 2010 WL 3338343 (W.D. Pa. Aug. 23, 2010).....	16
<i>Pa. Empls. Benefit Trust Fund v. AstraZeneca Pharm. LP</i> , No. 6:09-cv-5003-Orl-22DAB, 2009 WL 2231686 (M.D. Fla. July 20, 2009).....	14
<i>Parkinson v. Guidant Corp.</i> , 315 F. Supp. 2d 741 (W.D. Pa. 2004).....	8, 9
<i>Penk v. Or. State Bd. Of Higher Educ.</i> , 99 F.R.D. 508 (D. Or. 1982).....	14
<i>Perry v. Markman Capital Mgmt., Inc.</i> , No. 02-744, 2002 WL 31248038 (E.D. Pa. Oct. 4, 2002)	25
<i>Peter v. Stryker Orthopaedics, Inc.</i> , 581 F. Supp. 2d 813 (E.D. Mich. 2008).....	12
<i>Pippet v. Waterfront Dev. Co., LLC</i> , 166 F. Supp. 2d 233 (E.D. Pa. 2001)	23
<i>Prado-Steiman ex rel. Prado v. Bush</i> , 221 F.3d 1266 (11th Cir. 2000)	6
<i>Ramsey v. Summers</i> , No. 10-CV-00829, 2011 WL 811024 (W.D. Pa. Mar. 1, 2011)	7

Table of Authorities (cont'd)

	Page(s)
<i>Ross v. Fed. Deposit Ins. Corp.</i> , 625 F.3d 808 (4th Cir. 2010)	13
<i>Santana Prods., Inc. v. Bobrick Washroom Equip.</i> , 14 F. Supp. 2d 710 (M.D. Pa. 1998)	5
<i>Schroeder v. Ear, Nose and Throat Assocs. of Lehigh Valley, Inc.</i> , 557 A.2d 21 (Pa. Super. Ct. 1989)	15
<i>Simmens v. Coca Cola Co.</i> , No. 07-668, 2007 WL 2007977 (E.D. Pa. July 7, 2007)	20
<i>Smith v. HireRight Solutions, Inc.</i> , No. 09-6007, 2010 WL 2270541 (E.D. Pa. June 7, 2010)	19
<i>Snyder v. ISC Alloys Ltd.</i> , 772 F. Supp. 244 (W.D. Pa. 1991)	5
<i>Soufflas v. Zimmer, Inc.</i> , 474 F. Supp. 2d 737 (E.D. Pa. 2007)	9
<i>Surgical Laser Techs., Inc. v. C.R. Bard, Inc.</i> , 921 F. Supp. 281 (E.D. Pa. 1996)	5
<i>Taylor v. Smithkline Beecham Corp.</i> , 658 N.W.2d 127 (Mich. 2003)	9
<i>Triffin v. Harris Camden Terminals Corp.</i> , 79 B.R. 208 (E.D. Pa. 1987)	20
<i>TriState HVAC Equip. LLP v. Big Belly Solar, Inc.</i> , --F. Supp. 2d--, 2010 WL 4139285 (E.D. Pa. 2010)	24
<i>Turner v. Mandalay Sports Entm't, LLC.</i> , 180 P.3d 1172 (Nev. 2008)	15
<i>U.S. ex rel. FLFMC, LLC v. EBSCO Indus., Inc.</i> , No. 10-231, 2011 WL 825685 (W.D. Pa. Jan. 28, 2011)	18, 19
<i>U.S. ex rel. FLFMC, LLC v. T.F.H. Publ'ing</i> , No. 2:10cv437, 2010 WL 4181151 (W.D. Pa. Oct. 20, 2010)	19
<i>Von Pein v. Ciccotelli</i> , No. 94-CV-79527, 1995 WL 79527 (E.D. Pa. Feb. 17, 1995)	5
<i>Weber v. Basic Comfort, Inc.</i> , 155 F. Supp. 2d 283 (E.D. Pa. 2001)	24

Table of Authorities (cont'd)

	Page(s)
<i>White v. SmithKline Beecham Corp.</i> , 538 F. Supp. 2d 1023 (W.D. Mich. 2008)	9
<i>Winer Family Trust v. Queen</i> , 503 F.3d 319 (3d Cir. 2007).....	6
<i>Wolfe v. McNeil-PPC, Inc.</i> , 703 F. Supp. 2d 487 (E.D. Pa. 2010)	6
<i>Zafarana v. Pfizer</i> , 724 F. Supp. 2d 545 (E.D. Pa. 2010)	11
<i>Zeni v. Anderson</i> , 243 N.W. 2d 270 (Mich. 1976).....	6
STATUTES	
42 PA. CONS. STAT. § 5322(a)(4)	4
28 U.S.C. § 1391(b)	17
28 U.S.C. § 1404(a)	1, 3, 15
35 U.S.C. § 203	10
Bayh-Dole Act, 35 U.S.C. § 200, <i>et seq.</i>	2, 6
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 <i>et seq.</i>	2, 12
M.G.L. ch. 23I.....	24
M.G. L. ch. 62C, § 67D	24
M.G.L. ch. 111L, § 9	24
MICH. COMP. LAWS ANN. § 445.904(1)(a).....	12
MICH. COMP. LAWS ANN. § 600.2945(h)	9
MICH. COMP. LAWS ANN. § 600.2946(5)	9
NEV. REV. STAT. ANN. § 598.0955	11
Orphan Drug Act, 21 U.S.C. § 360aa <i>et seq.</i>	2, 12
Public Health Service Act, 42 U.S.C. § 262 <i>et seq.</i>	2, 12
WASH. REV. CODE ANN. § 5.40.050	7

Table of Authorities (cont'd)

	Page(s)
WASH. REV. CODE § 62A.2-103(1)(a).....	10
OTHER AUTHORITIES	
21 C.F.R § 316.....	12
105 C.M.R. § 480.200.....	24
310 C.M.R. § 7.03(25).....	24
Fed. R. Civ. P. 8.....	1, 3, 8
Fed. R. Civ. P. 12(b)(2).....	1
Fed. R. Civ. P. 12(b)(6).....	1, 8, 9
U.S. Const. Am. XIV.....	3

Defendants bring this three-part motion seeking (i) dismissal pursuant to Fed. R. Civ. P. 12(b)(2) as to defendant Mount Sinai School of Medicine (“Mt. Sinai”), over which this Court lacks personal jurisdiction; (ii) dismissal of the counts asserted against Genzyme Corporation (“Genzyme”) and Mt. Sinai for insufficient specificity and failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 8(a) and 12(b)(6) respectively; and (iii) transfer of any surviving claims in accordance with 28 U.S.C. § 1404(a), for the convenience of the parties and witnesses and in the interest of justice, to the United States District Court for the District of Massachusetts, where the physical facility, witnesses and documents are located and where litigation addressing certain key factual predicates to plaintiffs’ claims is already underway.¹

For purposes of this Motion only, Defendants accept the allegations of the Complaint.

Plaintiffs in this action are residents of the states of Michigan, North Carolina, Nevada, Washington and the Commonwealth of Pennsylvania. Compl., ¶¶ 1-11. Each either suffers from Fabry disease, a rare and incurable genetic illness, or is the spouse of a named Plaintiff who suffers from that disease. Compl., ¶¶ 1-11, 17. Plaintiffs’ complaints in this case are with respect to Fabrazyme, a treatment for Fabry disease that is manufactured by defendant Genzyme. Compl., ¶¶ 18, 20, 24.

Genzyme is a leading biotechnology company that focuses on the development of products to treat patients suffering from rare inherited disorders and other serious conditions. One segment of the company’s business develops and manufactures products that treat lysosomal

¹ While this motion is pending, Defendants’ time to Answer is tolled. *See, e.g., Alex. Brown Sons Inc. v. Marine Midland Banks, Inc.*, 96 Civ. 2549 (RWS), 1997 WL 97837, at *6-7 (S.D.N.Y. Mar. 4, 1997); *Circuit City Stores, Inc., v. Citgo Petroleum Corp.*, No. CIV. A. 92-CV-7394, 1994 WL 483463, at *4 (E.D. Pa. Sept. 7, 1994).

storage diseases—metabolic disorders (like Fabry disease) caused by a lack of certain enzymes. Fabrazyme is one of these biologic products, and is manufactured by Genzyme in Massachusetts, where Genzyme’s headquarters are also located. Compl., ¶¶ 12, 29. Fabrazyme is regulated under federal law. *See, e.g.* Public Health Service Act, 42 U.S.C. § 262 *et seq.* (hereinafter the “PHSA”); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (hereinafter the “FDCA”); Orphan Drug Act, 21 U.S.C. § 360aa *et seq.* (hereinafter “ODA”). Fabrazyme must be prescribed by a physician. *See* Compl., Ex. A.

Mt. Sinai² is named as a defendant solely on the basis of its limited title to a patent used in the manufacture of Fabrazyme, which it has licensed to Genzyme. Compl., ¶ 13. This licensing arrangement does not establish sufficient ties between Mt. Sinai and Pennsylvania to permit this Court to exercise personal jurisdiction over Mt. Sinai. *See infra* Part I.

Though styled as a series of causes of action under federal law, state common law and state statutory law, Plaintiffs in essence complain that Genzyme is not manufacturing Fabrazyme quickly enough, well enough “and/or” in sufficient quantities to meet demand. These same complaints have been previously aired when, in August of 2010, three named Plaintiffs in this action petitioned the National Institutes of Health (NIH) pursuant to the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.*, advancing essentially the same allegations raised here, and requesting that the NIH exercise rights provided under the Act to “march-in” and grant an open license for entities other than Genzyme to manufacture Fabrazyme. The NIH denied this petition, noting the steps that Genzyme is taking to address Fabrazyme shortages. Having failed in their claims once before the NIH, Plaintiffs now seek to advance them again in this Court, shoehorning them into causes of action that do not fit.

² Mt. Sinai School of Medicine operates as an independent entity from the City University of New York and, in this respect, is incorrectly described in the Complaint.

As set out below, *infra* Part II, virtually all of Plaintiffs' claims fail as a matter of law to state a claim upon which relief can be granted. Indeed, Plaintiffs' claims are so vaguely pled that they fail to meet the minimum standards articulated under Fed. R. Civ. P. 8 and the guidance of the U.S. Supreme Court. To the extent that any claims survive this Motion, in accordance with 28 U.S.C. § 1404(a) this Court should transfer them to the District of Massachusetts for the convenience of the parties and witnesses and in the interest of justice. *See infra*, Part III.

I. MT. SINAI MUST BE DISMISSED FOR LACK OF PERSONAL JURISDICTION

Pennsylvania lacks both general and specific personal jurisdiction over Mt. Sinai. Mt. Sinai is an education corporation organized and existing under the laws of the State of New York, with its headquarters and principal place of business located in New York. Compl., ¶ 13. Mt. Sinai is not alleged to conduct business in Pennsylvania and, in fact, conducts no business in Pennsylvania. Instead, Plaintiffs' allegations of contacts with Pennsylvania inexplicably turn on the patent license between Mt. Sinai (in New York) and Genzyme (in Massachusetts) Compl., ¶ 13. As is alleged, Mt. Sinai "exclusively licensed" patent rights relating to the manufacture of Fabrazyme to Genzyme, Compl., at ¶ 24. That is to say, Mt. Sinai ***does not*** manufacture Fabrazyme or have a role in that process; rather its sole connection is a patent license into which it entered in 1995.³

A federal district court may assert personal jurisdiction over a nonresident only to the extent permitted under the Constitution's due process clause. *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982); U.S. Const. Am. XIV. A proper analysis considers both general and specific jurisdiction, neither of which is established here.

³ A public version is on file with the SEC. *See* Genzyme Corp., Quarterly Report (Form 10-Q, Ex. 10.10) (Aug. 9, 2010), www.sec.gov/Archives/edgar/data/732485/000104746910007260/a2199511zex-10_10.htm.

A. Pennsylvania Lacks General Jurisdiction.

General jurisdiction is based upon “continuous and systematic contacts” with the forum. *Gen. Elec. Co. v. Deutz AG*, 270 F.3d 144, 150 (3d Cir. 2001) (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414-16 (1984)). No such contacts exist here, nor have they been alleged.⁴ The only jurisdictional allegation relevant to Mt. Sinai—the patent license between Mt. Sinai and Genzyme—is insufficient to create general personal jurisdiction. *See Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918, 923 (N.D. Ill. 2002) (although defendant granted licenses to patent to a facility in the Illinois, the state lacked general personal jurisdiction over the defendants). General jurisdiction cannot be established with regard to Mt. Sinai.

B. Pennsylvania Lacks Specific Jurisdiction.

Specific jurisdiction is established when the defendant “purposefully availed itself of the benefits and obligations of the forum” and plaintiff’s claim arises out of at least one of those activities. *Helicopteros Nacionales de Colombia, S.A.*, 466 U.S. at 414. Although Pennsylvania’s long arm statute extends to anyone who causes a tortious injury in Pennsylvania through acts or omissions outside Pennsylvania, the court must examine whether the defendant has sufficient minimum contacts with the forum state and whether the exercise of personal jurisdiction comports with the notions of fair play and substantial justice. 42 PA. CONS. STAT. § 5322(a)(4) (2004). *See Int’l Shoe, Co., v. Washington*, 326 U.S. 310, 316 (1945).

⁴ General contact that Mt. Sinai may have with Pennsylvania, such as students or staff who live in the state, or advertising in national publications that circulate in Pennsylvania, are the contacts of any nationally recognized school and are not sufficient for personal jurisdiction. *See Gehling v. St. George’s Sch. of Med., Ltd.*, 773 F.2d 539, 542 (3d Cir. 1985); *Corrales Martin v. Clemson Univ.*, No. 07-CV-536, 2007 WL 4531028 *5-7 (E.D. Pa. Dec. 20, 2007).

Plaintiffs do not allege conduct by Mt. Sinai in Pennsylvania, or contact connecting its claims against Mt. Sinai to any conduct in Pennsylvania. Mt. Sinai did not target Pennsylvania, nor avail itself of the opportunity to do business there. It is not responsible for where or to whom Fabrazyme is sold and cannot be subject to personal jurisdiction because of a third party's unilateral activities. *See Greenberg*, 208 F. Supp. 2d at 924; *Santana Prods., Inc. v. Bobrick Washroom Equip.*, 14 F. Supp. 2d 710, 715 (M.D. Pa. 1998) (“[i]n the absence of any contacts with Pennsylvania, the fact that harm is felt in Pennsylvania from conduct occurring outside Pennsylvania is not sufficient to satisfy due process unless the defendant targets Pennsylvania through the tortious conduct”); *see also Driscoll v. Matt Blatt Auto Sales*, No. 95-CV-5314, 1996 WL 156366, at *2 (E.D. Pa. Apr. 3, 1996); *Von Pein v. Ciccotelli*, No. 94-CV-79527, 1995 WL 79527, at *2 (E.D. Pa. Feb. 17, 1995); *Surgical Laser Techs., Inc. v. C.R. Bard, Inc.*, 921 F. Supp. 281, 285 (E.D. Pa. 1996) (“Foreseeability of harm within the forum state must be accompanied by conduct directed at the forum state in order for the defendant to reasonably anticipate being hailed into the state’s courts”); *Supra Med. Corp. v. McGonigle*, 955 F. Supp. 374, 382 (E.D. Pa. 1997). There has been no targeting of Pennsylvania by Mt. Sinai, and Mt. Sinai must be dismissed for lack of personal jurisdiction.

In addition, Plaintiffs fail to state a claim as to which relief can be granted against Mt. Sinai for all the reasons described in Part II, *infra*.⁵ Defendants request that such arguments be considered as to Mt. Sinai in the alternative, should the Court deny the jurisdictional motion.

⁵ Plaintiffs’ breach of warranty claims against Mt. Sinai also fail because no allegations connect Mt. Sinai to the sale of Fabrazyme. *See, e.g., Snyder v. ISC Alloys Ltd.*, 772 F. Supp. 244, 253 (W.D. Pa. 1991) (licensor not liable for breach of warranty because it did not “sell” a “good”); *Burkert v. Petrol Plus of Naugatuck*, 579 A.2d 26, 35 (Conn. 1990) (same result).

II. AS A MATTER OF LAW, AND UNDER RELEVANT PLEADING STANDARDS, PLAINTIFFS' CLAIMS AGAINST GENZYME MUST BE DISMISSED

A. Plaintiffs' Negligence *Per Se* Count Fails As A Matter of Law.

As a matter of law, Count II of the Complaint must be dismissed. The law of each jurisdiction potentially implicated by the Complaint⁶ bars a claim for negligence *per se* predicated on alleged violations of either the FDCA or the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.* Those federal statutes are pled as the basis for plaintiffs' claims here. Compl., ¶. 75.

Michigan “does not subscribe to the doctrine of negligence *per se*.” *Candelaria v. B.C. Gen. Contractors, Inc.*, 600 N.W. 2d 348, 356 (Mich. Ct. App. 1999); *see also Zeni v. Anderson*, 243 N.W. 2d 270, 280-83 (Mich. 1976).

In suits involving North Carolina law, federal courts have dismissed negligence *per se* claims based upon the FDCA; the decisions of these courts demonstrate that a claim in North Carolina for a violation of the Bayh-Dole Act would necessarily fail as well.⁷ *In re Aredia and Zometa Prod. Liab. Litig.*, No. 3-06-MD-1760, 2010 WL 5072022, at *2 (M.D. Tenn. Dec. 7, 2010); *Baraukas v. Danek Med., Inc.*, No. 97-CV-00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000); *Hill v. Danek Med., Inc.*, No. 96-CV-177, 1998 WL 1048182, at *3 (E.D.N.C. Sept. 10, 1998). Applying Nevada law, the District of Nevada dismissed an FDCA-based

⁶ Federal courts applying Pennsylvania choice of law rules have applied the law of a plaintiff's state in cases involving alleged injury by prescription medications. *See, e.g., Bearden v. Wyeth*, 482 F. Supp. 2d 614, 622 (E.D. Pa. 2006); *Wolfe v. McNeil-PPC, Inc.*, 703 F. Supp. 2d 487, 494 (E.D. Pa. 2010); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 616 (E.D. Pa. 2008); *In re Diet Drugs Litig.*, No. 98-CV-20626, 1999 WL 673066, at *15 (E.D. Pa. Aug. 26, 1999). There is no need for the Court to consider hypothetical plaintiffs not part of the litigation. *See Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007); *Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1279-80 (11th Cir. 2000); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 157-58 (E.D. Pa. 2009) (holding plaintiffs in putative class action may not bring claims under the laws of states where no named plaintiff resides or was injured).

⁷ Also, the Bayh-Dole Act does not qualify as a “public safety statute” that prescribes an enforceable standard of care, a pre-requisite for negligence *per se* actions in North Carolina. *See, e.g., Mosteller v. Duke Energy Corp.*, 698 S.E. 2d 424, 431-32 (N.C. Ct. App. 2010).

negligence *per se* claim using reasoning that applies with equal force to a claim premised on the Bayh-Dole Act. *See Miller v. DePuy Spine, Inc.* 638 F. Supp. 2d 1226, 1231 (D. Nev. 2009).

In Pennsylvania, there is no separate cause of action for negligence *per se* predicated on violations of a federal statute—as explained by the Third Circuit, an independent cause of action for negligence *per se* under the FDCA would impermissibly permit plaintiffs to recover directly for a violation of federal law. *See In re Orthopedic Bone Screw Prod. Liab. Litig.*, 193 F.3d 781, 790-92 (3d Cir. 1999); *see also Ramsey v. Summers*, No. 10-CV-00829, 2011 WL 811024, at *2 (W.D. Pa. Mar. 1, 2011). Finally, the state of Washington has abolished the action of negligence *per se* by statute. WASH. REV. CODE ANN. § 5.40.050 (2009).⁸

Because negligence *per se*, when predicated on alleged violations of either the FDCA or the Bayh-Dole Act, is not a viable cause of action under the law of the potentially relevant states, Count II must be dismissed in its entirety as a matter of law.

B. The Causes Of Action For Strict Liability Must Be Dismissed.

Count III of the Complaint fails to state a claim under the laws of Michigan, North Carolina, Pennsylvania, and Washington. Because, as described *supra*, Pennsylvania choice of law rules will apply the substantive law of each plaintiff's state, the claims under that count by all Plaintiffs in those states—*i.e.*, all Plaintiffs *other than* Joseph Carik⁹—must be dismissed on Rule 12(b)(6) grounds.

⁸ There are four statutory exceptions to this rule, none applicable here. WASH. REV. CODE ANN. § 5.40.050 (2009).

⁹ Though Nevada law recognizes strict liability claims in certain instances, claims grounded in labeling or dosage (a total of four out of the five alleged bases for liability under Count Three) do not satisfy the Nevada definition of “defect.” *See, e.g., Allison v. Merck and Co., Inc.*, 878 P.2d 948, 952 (Nev. 1994) (*citing Ginnis v. Mapes Hotel Corp.*, 470 P.2d 135, 138 (Nev. 1970)). It is unclear from the vague “and/or” pleading address below, *infra* Part II.F, whether the fifth alleged basis applies to Mr. Carik, and his claim under Count Three should be dismissed on the basis of that vagueness for failing to satisfy the specificity requirement of Fed. R. Civ. P. 8 (a)(2).

Neither Michigan nor North Carolina recognize strict liability in product liability actions. *See, e.g., Johnson v. Chrysler Corp.*, 254 N.W. 2d 569, 571 (Mich. Ct. App. 1977); *Driggers v. Sofamor, S.N.C.*, 44 F. Supp. 2d 760, 766 (M.D.N.C. 1999). Pennsylvania has ruled that strict liability is precluded for product liability actions involving prescription medications. *See Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741 (W.D. Pa. 2004) (*citing Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996)). And the state of Washington has enacted a statutory scheme concerning product liability law that preempts all “traditional common law remedies for product-related harms.” *Laisure-Radke et al., v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1168 (W.D. Wash. 2006) (*citing Wash. Water Power Co. v. Graybar Elec. Co.*, 774 P.2d 1199 (Wash. 1989)). Accordingly, the Court should dismiss the Count III claims of all Plaintiffs other than Mr. Carik pursuant to Fed. R. Civ. P. 12(b)(6), and, as to Mr. Carik, pursuant to Fed. R. Civ. P. 8(a)(2).

C. Plaintiffs’ Causes Of Action For Breach Of Express And Implied Warranties Fail As A Matter Of Law.

1. Plaintiffs Fail To Allege The Existence Of Any Express Warranty.

The Complaint does not state a claim for breach of express warranty under the laws of Michigan, Nevada, North Carolina, Pennsylvania, or Washington. In all of these states, plaintiffs must point to a specific representation upon which they relied. General assertions that such a warranty was made are insufficient.¹⁰ No such statement has been alleged; Plaintiffs’ claims for

¹⁰ *See Kester v. Zimmer Holdings, Inc.*, No. 2:10-CV-00523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010) (“Plaintiff neither specifies any particular promise...nor does she demonstrate any promise was directed at her...to induce her into purchasing the product.”); *Harbour Point Homeowners Assoc., Inc. v. DJF Enters., Inc.*, 697 S.E.2d 439, 447 (N.C. Ct. App. 2010); *Miller*, 638 F. Supp. 2d at 1229-30; *Heritage Resources, Inc. v. Caterpillar Fin. Servs. Corp.*, 774 N.W.2d 332, 342 n.11 (Mich. Ct. App. 2009); *Kelley v. Jacobs*, No. 21953-1-II, 1999 WL 305232, at *5 (Wash. Ct. App. May 14, 1999). Plaintiffs’ express warranty claims also fail under Washington law because, as discussed *infra*, no Fabrazyme was sold there, and because they are pled as common law claims and not, as required, under Washington’s statutory regime of product liability. *See Laisure-Radke*, 426 F. Supp. 2d at 1168 (*citing Wash. Water Power Co.*, 774 P.2d at 1199.).

breach of express warranty contained within Count IV should be dismissed in their entirety under Fed. R. Civ. P. 12 (b)(6) for failure to state a claim upon which relief can be granted.

2. Plaintiffs' Implied Warranty Claims Fail As A Matter Of Law.

Under Michigan law, “a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable” as long as the drug and its labeling have been approved by the FDA, and such approval was not fraudulently obtained.¹¹ MICH. COMP. LAWS ANN. § 600.2946(5) (West 2011); *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). This immunity applies to all “actions based on a legal or equitable theory of liability” in connection with harm allegedly caused by a prescription drug, MICH. COMP. LAWS ANN. § 600.2945(h), including breach of warranty. *See White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1026, 1031 (W.D. Mich. 2008).¹² Fabrazyme is a prescription medication; therefore the claims of Thomas Olszewski for breach of implied warranty must be dismissed.

Pennsylvania courts have similarly held that claims for breach of implied warranty regarding prescription medications are barred. *See Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987) (finding that “the very nature of prescription drugs precludes claims for breach of the implied warranty of merchantability.”).¹³ Therefore the claims of Anita Hochendoner for breach of implied warranty must be dismissed.

¹¹ Fabrazyme is not a drug but a biologic treatment. There is, however, no principled distinction relevant to the interpretation of this or any other state law concerning prescription “drugs.”

¹² *See also In re Prempro Prods. Liab. Litig.*, 4:03-CV-1507-WRW, 4:04-CV-01202, 2008 WL 1699211, at *4 (E.D. Ark. Apr. 9, 2008) (“Under Michigan law, when a drug has been approved for safety and efficacy by the [FDA] and carries an FDA-approved label at the time it left the control of the manufacturer or seller, ‘the manufacturer or seller is not liable’ in any product liability action.”) (citation omitted).

¹³ *See also Kester*, 2010 WL 2696467 at *11; *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 752 (E.D. Pa. 2007) (finding that both the implied warranties of merchantability and fitness do not apply to prescription drugs.); *Parkinson*, 315 F. Supp. 2d at 752-53.

Plaintiffs Amber and Shawn Britton have not been prescribed Fabrazyme, Compl., ¶¶ 42-45, 107, and hence could not rely on any warranty associated with its sale.¹⁴ See WASH. REV. CODE § 62A.2-103(1)(a) (2000) (buyer is “person who buys or contracts to buy goods”). Their claims for breach of implied warranty must therefore be dismissed. As described *infra* Part II.F, the claims of Plaintiffs Joseph M. Carik and David Roberts for breaches of the implied warranty under the laws of North Carolina and Nevada law fail because they are insufficiently pled.

D. The Bayh-Dole Act Does Not Establish An Implied Right of Action.

Count V purports to advance an implied cause of action under the Bayh-Dole Act. However, courts across the country have concluded when considering that Act that no such cause of action exists. See, e.g., *Fenner Inv., Ltd. v. Hewlett-Packard Co.*, No. 08-CV-273, 2010 WL 3275758, at *4 (E.D. Tex Apr. 15, 2010); *Madey v. Duke Univ.*, 413 F. Supp 2d. 601, 613 (M.D.N.C. 2006); *Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614, 629 (D.N.J. 1992).

In evaluating a federal statute to determine if an implied cause of action exists, the Supreme Court looks to both the statutory language itself and the accompanying legislative history to determine whether Congress intended to create a private cause of action. *Middlesex Cnty. Sewage Auth. v. Nat’l Sea Clammers Assoc.*, 453 U.S. 1, 13 (1981). Nothing in either the Bayh-Dole Act or its legislative history suggests that such a right of action was intended. The Act regulates “the relationship between the Government and its funding recipients, *not* the relationships between private parties.” *Madey*, 413 F. Supp. 2d. at 613 (emphasis added).

Moreover, the Bayh-Dole Act provides an express remedy (i.e., the “march-in” right) precisely aimed at the alleged harm that plaintiffs claim entitles them to an implied remedy. 35 U.S.C. § 203. Existence of an express remedy demonstrates that Congress did not intend to

¹⁴ The Complaint does not allege that Cheryl Britton has Fabry Disease. Her sole cause of action is loss of consortium. Compl., ¶ 107.

create an implied cause of action under the same statute. *Middlesex Cnty. Sewage Auth.*, 454 U.S. at 3. *See also Astra USA, Inc. v. Santa Clara Cnty.*, No. 09-1273, 2011 WL 1119021, *1 (U.S. March 29, 2011). Plaintiffs already exercised their express right under the Act; their request was denied. Compl., ¶ 61. Nothing suggests Congress intended to create an implied cause of action permitting another attempt to enforce the statute privately; Count IV must be dismissed.

E. Counts Alleging Statutory Violations Of State Consumer Protection Statutes Fail As A Matter Of Law.

Plaintiffs advance a series of claims under state consumer protection statutes—Counts VI, VII, VIII, and IX—none of which states a viable claim of action under relevant state laws.

1. Count VI Fails To State A Claim Under Pennsylvania Law.

Count VI fails because a patient’s prescribing physician breaks the chain of justifiable reliance required for a successful action under the Pennsylvania Unfair Trade Practices Consumer Protection Law (“UTPCPL”). *See Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 384 (D.N.J.2004); *Kester*, 2010 WL 2696467, at *14; *Zafarana v. Pfizer*, 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010); *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31-32 (Pa. Super. Ct. 2006). Fabrayzme is a prescription treatment. *See* Compl., Ex. A.

2. Counts VII And VIII Fail Under Nevada And Michigan Law, Respectively.

Counts VII and VIII must be dismissed because neither the Nevada Deceptive Trade Practices Act (“NDTPA”) nor the Michigan Consumer Protection Act (“MCPA”) applies to conduct regulated by state or federal law. *See* NEV. REV. STAT. ANN. § 598.0955 (West 2010)¹⁵

¹⁵ “The provisions of NRS 598.0903 to 598.0999, inclusive do not apply to: (a) conduct in compliance with orders or rules of, or a statute administered by, a federal, state, or local governmental agency.” NEV. REV. STAT. ANN. § 598.0955 (West 2011).

and MICH. COMP. LAWS ANN. § 445.904(1)(a) (West 2011).¹⁶ The manufacture, sale, and use of Fabrazyme, as a biologics product, are regulated under federal law. *See e.g.*, 42 U.S.C. § 262 *et seq.* (2010), 21 U.S.C. § 301 (2010), *et seq.*, 21 U.S.C. § 360aa (2010), *et seq.*, and 21 C.F.R. § 316 (2011). Plaintiffs' claims under Nevada and Michigan state consumer protection laws are therefore preempted. *See Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *7 (Mich. Ct. App. June 13, 2006) (holding that "[b]ecause the general marketing and advertising activities underlying plaintiff's MCPA claim are authorized and regulated under laws administered by the FDA, the exemption in M.C.L. 445.904(1)(a) applies to plaintiff's MCPA claim."). *See also Peter v. Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d 813 (E.D. Mich. 2008); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1021 (E.D. Mich. 1993).

3. Count IX Fails Under North Carolina Law.

Count IX purports to plead a claim under the North Carolina Unfair and Deceptive Trade Practice Act ("NCUDTPA"). North Carolina courts have not directly addressed orphan drugs under the NCUDTPA, but North Carolina precedent strongly suggests that the claims advanced under Count IX would be dismissed.

To state a viable claim at the pleading stage under the NCUDTPA, plaintiffs must allege "egregious or aggravating circumstances." *See Dalton v. Camp*, 548 S.E.2d 704, 711 (N.C. 2001) (*citing Allied Distribs., Inc. v. Latrobe Brewing Co.*, 847 F. Supp. 376, 379 (E.D.N.C. 1993)). Because the manufacture, use and sale of Fabrazyme are regulated by federal law, *supra* Part II.E.2, Plaintiffs cannot plead the "egregious or aggravating circumstances" required.

¹⁶ "This act does not apply to [...] a transaction or conduct specifically authorized under the laws administered by a regulatory board or officer acting under the statutory authority of this state or the United States." MICH. COMP. LAWS § 445.904(1)(a) (West 2011). *See also McLiechey v. Bristol West Ins. Co.*, 408 F. Supp. 2d 516, 523 (W.D. Mich. 2006) (*citing Smith v. Globe Life Ins. Co.*, 597 N.W.2d. 28, 38 (Mich. 1999)).

Courts applying North Carolina law have recognized this in refusing to recognize a cause of action under the NCUDTPA when the underlying transaction is regulated by federal law. *See e.g., Harrah v. J.C. Bradford & Co.*, 1994 WL 543528, *4 (4th Cir. 1994) (finding that NCUDTPA does not apply to securities transactions because of “pervasive and intricate” securities regulations under both state and federal law); *Ross v. Fed. Deposit Ins. Corp.*, 625 F.3d 808 (4th Cir. 2010) (finding that the Fair Credit Reporting Act preempted the NCUDPTA regarding reporting false credit information). Applying this reasoning, which parallels that applied by Michigan and Nevada courts, North Carolina would not recognize a claim under the NCUDPTA in connection with a federally regulated biologic treatment.

F. Plaintiffs’ Claims Are Vague And Insufficiently Pled.

Plaintiffs’ claims are designed to survive through obfuscation and vague “and/or” pleading. Plaintiffs are required to set forth in their pleadings clear factual allegations that support their legal conclusions. *Ashcroft v. Iqbal*, 556 U.S. ___, 129 S. Ct. 1937, 1939 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)). Plaintiffs have not done so; the Complaint’s factual allegations fail to connect the dots between the alleged actions of the Defendants and the alleged harm done to any particular plaintiff and therefore do not provide Defendants with proper notice. *See Twombly*, 550 U.S. at 555.

The Complaint’s core, and representative, allegation of harm consist of this vague sentence: “As a direct result of the Genzyme Rationing Plan **and/or** Genzyme’s denial of access to drug **and/or** sale of adulterated drug, **Fabry patients** have **either** had a return of symptoms, accelerated disease development, injury, and otherwise preventable disease progression, **or** have died during the shortage.” Compl., ¶ 62 (emphasis added). Similar “and/or” pleading is used throughout the Complaint in ways that preclude a meaningful response—*e.g.*, “breach of express **and/or** implied warranties of merchantability **or** fitness.” *Id.* ¶ 83 (emphasis added).

The use of “and/or” is disfavored, and is grounds for dismissal. *See, e.g., Gregory v. Dillard’s Inc.*, 565 F. 3d 464, 473 n.9 (8th Cir. 2009) (en banc) (noting use of “and/or” did “not connect any particular plaintiff to any particular allegation.”); *Pa. Empls. Benefit Trust Fund v. AstraZeneca Pharm. LP*, No. 6:09-cv-5003-Orl-22DAB, 2009 WL 2231686, at *3 (M.D. Fla. July 20, 2009) (dismissing claims in part because of “equivocal” use of “and/or”). Particularly problematic is the fact that no harm is alleged to have occurred to any specific Plaintiff, let alone any specific harm attributed to any particular action of a particular Defendant.¹⁷

The Supreme Court has directed that pleading deficiencies such as those identified here should “be exposed at the point of minimum expenditure of time and money by the parties and the court.” *Twombly*, 550 U.S. at 558. *See also Cooney v. Rossiter*, 583 F.3d 967, 971 (7th Cir. 2009) (noting dismissal is proper where minimum pleading standards are not met, and the “burden of discovery imposed . . . by implausible allegations perhaps intended merely to extort a settlement....”). Accordingly, this Court should use its authority to dismiss the pending Complaint in its entirety. This includes those claims not separately addressed *supra*: Count I (Negligence), the claim of Joseph M. Carik under Count III (Strict Liability), the claims of

¹⁷ Despite that plaintiffs purport to advancing a class action, they must properly plead facts that a named plaintiff was injured by defendants’ conduct and not depend on vague allegations that harm has come to some potential plaintiff somewhere based on some unspecified theory of liability. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996) (“[N]amed plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class....”); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, 570 F. Supp. 2d 851, 856 (E.D. La. 2008) (putative class action complaint deficient where it fails to link “particular [p]laintiff” to particular allegedly defective housing units); *Penk v. Or. State Bd. Of Higher Educ.*, 99 F.R.D. 508, 510 (D. Or. 1982) (same result where complaint “simply allege[s] that defendant caused certain injuries to some of the named plaintiffs, without specifying that a given named plaintiff has suffered any given injuries”).

Joseph M. Carik and David Roberts for breach of implied warranty under Count IV, and each claim advanced under Count X (Loss of Consortium).¹⁸

III. ANY REMAINING CLAIMS SHOULD BE TRANSFERRED TO THE DISTRICT OF MASSACHUSETTS.

To the extent this Court does not dismiss the Complaint in its entirety, any surviving counts should be transferred to the District of Massachusetts for the convenience of the parties and witnesses and in the interest of justice. *See* 28 U.S.C. § 1404 (a). During the relevant time period, Fabrazyme was manufactured in Massachusetts, more specifically at Genzyme's plants in Allston and Framingham. Compl., ¶¶ 29, 35, 37. Decisions concerning labeling and dosage recommendations in the wake of the supply constraints resulting from the June 2009 bioreactor contamination in Allston were made wholly or principally at Genzyme's facilities and corporate headquarters in Massachusetts. *Id.* ¶ 12 (Genzyme is headquartered and has its principal place of business in Massachusetts). Genzyme is not alleged to have (and, in fact, does not have) any significant manufacturing or corporate operations in Pennsylvania. Moreover, the majority of the Plaintiffs also have no alleged connection to or contact with Pennsylvania. *Id.* ¶¶ 4, 6-11.

"For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought."

28 U.S.C. § 1404(a). A court should transfer an action when it is shown that "the transferee

¹⁸ Count X fails for the additional reason that it cannot survive without underlying counts to support it. *See Schroeder v. Ear, Nose and Throat Assocs. of Lehigh Valley, Inc.*, 557 A.2d 21, 22 (Pa. Super. Ct. 1989); *Long v. Chelsea Cmty. Hosp.*, 557 N.W.2d 157, 162 (Mich. Ct. App. 1996), *abrogated on other grounds by Feyz v. Mercy Mem. Hosp.*, 719 N.W.2d 1 (Mich. 2006); *McLaurin v. East Jordan Iron Works, Inc.*, 666 F. Supp. 2d 590, 602 (E.D.N.C. 2009); *Turner v. Mandalay Sports Entm't, LLC.*, 180 P.3d 1172, 1178 (Nev. 2008); *Francom v. Costco Wholesale Corp.*, 991 P.2d 1182, 1195 (Wash. App. Div. 2000); *Conradt v. Four Star Promotions Inc.*, 728 P.2d 617, 622 (Wash. App. Div. 1986).

venue is clearly more convenient than the venue chosen by the plaintiff.” *In re Genentech, Inc.*, 566 F.3d 1338, 1342 (Fed. Cir. 2009).

If venue is proper in the transferee district, courts in the Third Circuit may consider the following “private interests” in deciding a motion to transfer: “(1) each party’s forum preference; (2) where the claim arose; (3) the convenience of the parties as indicated by their relative physical and financial conditions; (4) the convenience of the witnesses; and (5) the locations of books and records.” *National Asset Mgmt. v. Coleman*, No. 10-16, 2010 WL 3338343, at *3 (W.D. Pa. Aug. 23, 2010) (citing *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995)). In addition, the court may weigh six “public interests”: “(1) enforceability of the judgment; (2) practical considerations that could make the trial easy, expeditious or inexpensive; (3) the relative administrative difficulty in the two fora resulting from court congestion; (4) the local interest in deciding local controversies at home; (5) the public policies of the fora; and (6) the familiarity of the trial judge with the applicable state law in diversity cases.” *National Asset Mgmt.*, 2010 WL 3338343, at *3 (citation omitted).¹⁹

Weighing the relevant factors in light of the facts briefly summarized above, the balance of both private and public factors significantly favors the transfer of this case to the District of Massachusetts.

¹⁹ At present, there is no reason to believe that a judgment issued in Massachusetts would not be enforceable elsewhere. Thus, this factor is neutral. In addition, there is no greater congestion, nor is there less efficiency, in Massachusetts as compared with the Western District of Pennsylvania. Recent statistics indicate that between September 2009 and September 2010, 2,435 civil matters were commenced in this Court while 2,498 were terminated. Data from the District of Massachusetts covering the same period indicates a substantially comparable level of congestion (2,906 cases commenced with 2,683 concluded). Any marginal increases in case volume in Massachusetts is arguably offset by that district’s relatively greater number of active judges (thirteen active judges, versus eight in the Western District of Pennsylvania). On balance, this factor is also neutral in the transfer analysis.

A. This Action Could Have Been Brought In Massachusetts.

Massachusetts would have been an appropriate forum in which to file this action. In cases such as this one, where subject matter jurisdiction is predicated upon both the presence of a federal question as well as the parties' diversity of citizenship, venue is proper in any district "in which a substantial part of the events or omissions giving rise to the claim occurred." 28 U.S.C. § 1391(b). Here, virtually all of the alleged conduct underlying Plaintiffs' claims occurred in Massachusetts, as the Complaint itself acknowledges. Compl., ¶¶ 13, 29, 35, 37.

B. The Private Interest Factors Weigh In Favor Of Transfer.

1. The Balance Of The Parties' Preferences Favors Transfer.

The Third Circuit's *Jumara* standard expressly provides that defendants' forum preferences should be considered, as well as those of plaintiffs. *Jumara*, 55 F.3d at 879. Here, Plaintiffs hope to create a class of "any and all individuals residing in the United States who have been diagnosed with Fabry disease, and their spouses," Compl., ¶ 64. With such a professed desire, Plaintiffs' choice of forum must "be accorded less deference...since all members of the class could conceivably bring suit in his or her home forum." Consequently "[t]he focus of the litigation will be on [defendant's] actions, not on any class members' actions." *Klingensmith v. Paradise Shops, Inc.*, No. 07-322, 2007 WL 2071677, at *2 (W.D. Pa. July 17, 2007) (quotation omitted) (granting motion to transfer). That concept applies with particular force in this case where only four named Plaintiffs reside in Pennsylvania, while seven reside in Nevada, Washington, Michigan, and North Carolina. Compl., ¶¶ 4, 6-11.

2. Plaintiffs' Claims Arose In Massachusetts.

This Court has consistently recognized that products liability claims "do[] not have a single 'situs.'" *Brown v. Kia Motors Corp.*, No. 2:06-cv-804, 2007 WL 539652, at *3 (W.D. Pa. Feb. 15, 2007). Considerable weight is accorded to the location where the product was designed,

manufactured, and marketed. *See Kettavong v. Gasbarre Prods., Inc.*, No. 07-00810, 2007 WL 2728413, at *3 (W.D. Pa. Sept. 17, 2007) (“Being that this is a products liability action, the claim ‘arose’ here in the sense that the equipment was designed and manufactured within this District.”); *U.S. ex rel. FLFMC, LLC v. EBSCO Indus., Inc.*, No. 10-231, 2011 WL 825685, at *8 (W.D. Pa. Jan. 28, 2011) (granting motion to transfer in part because the product at issue was made, marketed, and distributed in transferee jurisdiction).

In the instant case, Plaintiffs’ allegations center on “defects” and failures to adequately warn and label in connection with the production, labeling, and sale of Fabrazyme, Compl., ¶ 79. Almost all of the challenged activities occurred in Massachusetts. In contrast, none of the allegedly offending conduct took place in, or related to, Pennsylvania. And, while the site of a plaintiff’s alleged injury may be taken into account, it “is not a compelling” consideration. *Brown*, 2007 WL 539652, at *3; *Duvall v. Avco Corp.*, No. 4:CV05-1786, 2006 WL 723484, at *2 (M.D. Pa. Jan. 30, 2006) (“[T]he claims asserted...are of a product liability nature, therefore the physical location of the accident carries less weight....”). *See also Kettavong*, 2007 WL 2728413, at *1, *3 (plaintiff’s inclusion of negligence and loss of consortium claims did not alter conclusion that claim arose where allegedly defective product was manufactured).

3. Massachusetts Is The More Convenient Forum For The Parties and Witnesses.

The convenience of the parties and witnesses also militates strongly in favor of transfer to Massachusetts. Although this factor is concerned primarily with the accommodation of non-party witnesses (which neither side in this case has yet named), this Court has repeatedly recognized its applicability to party witnesses as well. For example, in *Klingensmith*, the Court noted that since the focus of the litigation would likely be the corporate defendant’s (rather than the plaintiff’s) conduct, the testimony of the defendant’s officers and employees would likely

prove critical. *See* 2007 WL 2071677, at *3. The fact that most of the defendant company’s “senior officers and key decision makers” resided in the transferee state thus weighed in favor of transfer. *Id.* The same is true in the instant case.

Moreover, since virtually all of Genzyme’s senior personnel and major decision makers are located in Massachusetts, transfer would reduce disruption to the Company’s operations at a time when Genzyme is working hard to address supply issues, and to meet the needs of its patient communities, all as Plaintiffs profess to desire. *See U.S. ex rel. FLFMC, LLC v. T.F.H. Publ’ing*, No. 2:10cv437, 2010 WL 4181151, at *3 (W.D. Pa. Oct. 20, 2010) (reasoning that “the absence of...officers and employees [who may be called to testify] would be very disruptive to [defendant]’s business operations”).

By contrast, a majority of the Plaintiffs—who are located in states other than Pennsylvania—will inevitably incur inconveniences regardless of whether the Court grants a transfer. *See Smith v. HireRight Solutions, Inc.*, No. 09-6007, 2010 WL 2270541, at *6 (E.D. Pa. June 7, 2010) (granting transfer and explaining that although plaintiff resides in Pennsylvania, retaining the case there “is not necessarily convenient to any of the other class members, who could reside anywhere in the United States”).

4. Books, Records, And Key Sources Of Proof Are In Massachusetts.

Although access to books and records is accorded less weight in the digital era, it is still a factor to be evaluated in the transfer analysis. *See Klingensmith*, 2007 WL 2071677, at *3 (taking into consideration the physical location of corporate defendant’s books and records). The fact that Genzyme may be called upon to produce a considerable volume of documents, the vast majority (if not all) of which are located in Massachusetts, further supports the transfer of this case to the District of Massachusetts. *See FLFMC*, 2011 WL 825685, at *4 (noting that the relevant business records as well as “persons with knowledge of the business records, the

marking, production, marketing and distribution of the” product at issue were in the transferee state).

Furthermore, courts in the Third Circuit have recognized that access to other sources of proof is also pertinent. *See, e.g., Decker v. Marriott Hotel Servs.*, No. 06-3191, 2007 WL 1630097, at *1 (E.D. Pa. June 4, 2007). Here, Plaintiffs’ allegations are deeply intertwined with the maintenance and operations of Genzyme’s manufacturing facility in Allston, Massachusetts. That site and the physical equipment located there—including the bioreactor that was the subject of the June 2009 contamination event—may be sources of evidence. Such a possibility weighs in favor of transfer. *See Triffin v. Harris Camden Terminals Corp.*, 79 B.R. 208, 209 (E.D. Pa. 1987) (“[T]ransfer will facilitate the possibility of viewing the premises where the equipment [implicated in the suit] is kept.”).

C. The Public Interest Factors Weigh In Favor Of Transfer.

1. Litigation In Massachusetts Involving The Same Facts Is A Practical Consideration Supporting Transfer.

Compelling practical considerations further reinforce the wisdom of transfer to Massachusetts, as numerous actions implicating the same set of operative facts as those underlying Plaintiffs’ claims in the instant suit have been pending against Genzyme in Massachusetts for well over a year. Courts in the Third Circuit have consistently recognized, “the presence of related cases in the transferee forum...alone is sufficient to warrant a transfer.” *Simmens v. Coca Cola Co.*, No. 07-668, 2007 WL 2007977, at *2 (E.D. Pa. July 7, 2007); *Mylan, Inc. v. Boehringer Ingelheim Int’l*, No. 09-990, 2010 WL 1142040, at *5 (W.D. Pa. Mar. 24, 2010). Such a precept is rooted in a practical but crucial concern for judicial economy. *See Simmens*, 2007 WL 2007977, at *3.

On July 29, 2009 and August 3, 2009, putative class action suits (subsequently consolidated) were filed under the federal securities laws against Genzyme and certain of its officers and directors in the District of Massachusetts. Shareholder derivative suits premised on the same alleged facts were subsequently filed in both federal and state court in Massachusetts between December 2009 and March 2010. All of these actions are predicated upon Genzyme's alleged conduct in connection with manufacturing and compliance issues at the Allston Landing Facility, the viral contamination that affected the Allston plant in June 2009, and the discovery of particulate matter in certain vials of product in November 2009. For example, included in the consolidated class action complaint are extensive discussions of allegations identical to ones raised by Plaintiffs here, including Genzyme's alleged "failures" "to implement necessary practices and procedures to prevent microbial or viral contamination at Allston," (¶¶ 58-63), and "to properly purify its drugs, protect against particulate contamination of the drug product, and ensure quality" of biologics including Fabrazyme (¶¶ 64-71). *See Consolidated Compl., In re Genzyme Corp. Sec. Litig.*, 1:09-cv-11267-GAO (D. Mass. filed Mar. 1, 2010). The consolidated complaint similarly sets out at length allegations concerning "deficiencies with Allston's manufacturing practices," (¶¶ 79-82) as well as the February 2009 Warning Letter (¶¶ 112-27).²⁰

²⁰ On February 16, 2011, Genzyme and sanofi-aventis, S.A. ("sanofi"), a French *société anonyme*, announced they had reached an agreement on a plan and agreement of merger, pursuant to which sanofi would amend its previous tender offer to provide for the purchase of all of Genzyme's outstanding shares. A subsequent tender offer period was announced and the merger has not yet been completed. Once the merger is completed, however, there will no longer be any public shareholders of Genzyme shares, and, as a result, no shareholders will maintain the 'continuous ownership' of shares required to retain standing to pursue derivative claims on behalf of Genzyme. Thus, the derivative action currently pending in the District of Massachusetts will be subject to dismissal. *Billings v. GFTM, LLC*, 867 N.E.2d 714, 724-25 (Mass. 2007). The federal securities class action, however, is unaffected by the Genzyme/sanofi merger and will remain pending in the federal court pending its resolution.

Furthermore, the actions pending in Massachusetts also incorporate facts and allegations regarding Genzyme's development and implementation of supply management strategies for its lysosomal storage disorder (LSD) biologics (including Fabrazyme). Specifically, the consolidated complaint filed in the shareholder litigation alleges decisions by Genzyme to reduce Fabrazyme inventories, thus leading to supply repercussions following the June 2009 contamination (¶¶ 83-84, 104-05). That the issues raised in the respective actions may not be perfectly coterminous or involve identical parties does nothing to alter this conclusion. *See Mylan*, 2010 WL 1142040, at *5 (explaining that transfer is appropriate as long as the proceedings are "related"; they need not be "inextricably intertwined"); *Jim Walter Corp. v. Cont'l Cas. Co.*, No. 91-3583, 1992 WL 162851, at *7 (D.N.J. June 1, 1992).

In sum, the allegations raised by Plaintiffs here implicate a series of highly technical factual questions pertaining to the nuances of biologics manufacturing, and the complex regulatory regime that governs those processes, which the District of Massachusetts has already been called upon to address. For this Court to undertake an entirely duplicative effort would not serve the goals of judicial efficiency and economy. *See CIBC World Mkts., Inc. v. Deutsche Bank Sec., Inc., et al.*, 309 F. Supp. 2d 637, 651 (D.N.J. 2004) (transfer appropriate where, even though parties were different, judge in transferee forum "already expended significant effort in familiarizing himself with this [related] case's highly complex factual background...."); *Ltd. Serv. Corp. v. M/V APL Peru*, No. 2:09-cv-1025, 2010 WL 2105362, at *5 (S.D. Ohio May 25, 2010) (transfer justified though actions were not identical because "substantial savings of judicial time and resources" would result).

2. Massachusetts' Particularized Interests In A Local Controversy Favor Transfer.

Because “a substantial amount of the alleged culpable conduct” alleged by Plaintiffs occurred in Massachusetts, the Commonwealth of Massachusetts has a significant interest in assuming jurisdiction over this case. *See Coppola v. Ferrellgas, Inc.*, 250 F.R.D. 195, 201 (E.D. Pa. 2008); *see also Fujitsu Ltd. v. Tellabs, Inc.*, 639 F. Supp. 2d 761, 769 (E.D. Tex. 2009) (“Because the accused products are designed and developed in [transferee forum] and Defendants’ principal places of business are located [there]...that district certainly has a particularized local interest in the dispute.”).

The biotechnology sector, and proper conduct within that industry, occupies a position of singular and pivotal importance to Massachusetts. *See infra*, Part III.B.3. Thus, regardless of the merits of the Plaintiffs’ claims, the fact remains that this action inescapably intersects with crucial and distinctive local interests in Massachusetts. *See B.R. Tank, LLC v. Holcim (US), Inc.*, No. A-09-CA-640, 2009 WL 3831379, at *5 (S.D. Tex. Nov. 12, 2009) (transferee district had “substantial local interest” given that defendant facility’s employees resided there and the facility had relationships with other local businesses). *See also Pippet v. Waterfront Dev. Co., LLC*, 166 F. Supp. 2d 233, 239 (E.D. Pa. 2001) (granting transfer, citing transferee state’s economic interests in the subject matter of the litigation).

3. Massachusetts' Public Policy Interests Favor Transfer.

For similar reasons, the issues raised by this lawsuit implicate public policy concerns of particular importance to Massachusetts. Massachusetts has enacted a host of statutes and regulations reflecting the significance of biotechnology firms to the state as well as the safety

issues endemic to the industry.²¹ Although these enactments do not govern Plaintiffs' specific causes of action in this case, they clearly evidence Massachusetts' distinctive underlying public policy interests in issues underlying Plaintiffs' allegations. *See Coppola*, 250 F.R.D. at 201 (transferee state's detailed administrative code governing the safety of the product at issue illustrated its public policy interest in the dispute). While Pennsylvania also has an interest in protecting its citizens from injury, this general, undifferentiated concern is common to all five states in which the individual Plaintiffs reside. Massachusetts' particularized interest suggests that this factor favors transfer. *See id*; *Fujitsu*, 639 F. Supp. 2d at 769.

4. Familiarity With Pennsylvania Law Would Not Provide A Significant Benefit.

Because “[f]ederal judges are frequently called upon to apply the laws of other states,” the judge’s familiarity with the applicable state law is not accorded significant weight in the decision whether to transfer. *See Coppola*, 250 F.R.D. at 203; *TriState HVAC Equip. LLP v. Big Belly Solar, Inc.*, --F. Supp. 2d--, 2010 WL 4139285, at *16 (E.D. Pa. 2010). This is particularly true in the instant case. To the extent they survive dismissal, Counts II and V of the Complaint are governed wholly or substantially by federal law, thus rendering this factor irrelevant as to them. *Weber v. Basic Comfort, Inc.*, 155 F. Supp. 2d 283, 286-87 (E.D. Pa. 2001). Counts VII, VIII, and IX, to the extent they survive, present questions arising under the statutory laws of Nevada, Michigan, and North Carolina, respectively. This Court and the District of Massachusetts are equally capable of adjudicating such non-forum claims. Counts I, III, IV, and X all articulate causes of action that are “strongly founded in common law which indicates that

²¹ *See, e.g.*, M.G.L. ch. 23I (establishing life sciences fund to invest in, inter alia, biotechnology); M.G. L. ch. 62C, § 67D (job creation inventive program aimed specifically at biotech firms); M.G.L. ch. 111L, § 9 (founding biomedical research advisory council “to promote biotechnology in the Commonwealth”); 105 CMR § 480.200; 310 CMR § 7.03(25) (setting forth various safety regulations applicable to biotech firms, including waste disposal and disinfection procedures).

neither venue is more appropriate.” *Perry v. Markman Capital Mgmt., Inc.*, No. 02-744, 2002 WL 31248038, at *11 (E.D. Pa. Oct. 4, 2002).

CONCLUSION

For the reasons set forth above, Defendant Mt. Sinai requests that it be dismissed from this suit, or, in the alternative, that the claims against it be dismissed for the reasons stated herein; Defendant Genzyme requests that the claims against it be dismissed on the grounds that they either fail to state a claim as a matter of law or have been insufficiently pled. To the extent that any claims remain, Defendants request that they be transferred to the District of Massachusetts.

Respectfully submitted,

Dated: April 4, 2011

By: /s/ Keith E. Whitson
John K. Gisleson (PA ID 62511)
Keith E. Whitson (PA ID 69656)
Emily M. Ayoub (PA ID 204891)
SCHNADER HARRISON SEGAL & LEWIS LLP
2700 Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222
(412) 577-5200
Fax: (412) 577-5190

Of counsel:

Joan A. Lukey
Catherine A. Mondell
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600